Message Text

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PAGE 01 STATE 174529
ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-12 ISO-00 OES-09 /040 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/NE RWOODS(INFO)
EA/ANP:TWAJDA(INFO)
EUR/NE:SWORREL(INFO)
----------092215 112042Z /15
P 111949Z JUL 78
FM SECSTATE WASHDC
TO AMEMBASSY STOCKHOLM PRIORITY
AMEMBASSY CANBERRA PRIORITY
AMEMBASSY LONDON PRIORITY

UNCLAS STATE 174529

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, SW, AS, UK

SUBJECT: FDA ADVISORY - MEDICAL DEVICE RECALL INADEQUATE PACKAGING/STERILITY (RECALL T-041-8)

1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL; PRODUCT INVOLVED - THE PRODUCT IS A TAVERNETTI-TENNANT-CUTTER KNEE PROSTHESIS. THE SIZES BEING RECALLED ARE THE SMALL AND STANDARD FOR BOTH LEFT AND RIGHT KNEES. THE DEVICE IS INTENDED TO BE STERILE AND IS PACKAGED IN A CLEAR POLYETHYLENE PLASTIC BAG WITH AN EXTERIOR CARTON. THE DEVICE IS PACKAGED AS TWO SEPARATE PARTS.

2. PRODUCT IDENTIFICATION - THE CARDBOARD BAOX AND INDIVIDUAL BAGS ARE LABELED IN PART: "CUTTER BIOMEDICAL... TABERNETTI-TENNANT CUTTER KNEE PROSTHESIS...CATALOG NO.... UNCLASSIFIED

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SIZE...SIDE... SERIAL NUMBER STERILE (IF INNER PACKAGE SEALED) CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN...."

3. AN INCLUDED DESCRIPTIVE WARNING STATEMENT READS IN PART: "CUTTER BIOMEDICAL...TAVERNETTI-TENNANT-CUTTER KNEE PROSTHESIS...INDICATIONS..CONTRAINDICATIONS ...WARNINGS...

PRECAUTIONS...ADVERSE EFFECTS..." A RECORD KEEPING STICKER INCLUDED READS IN PART: "CUTTER BIOMEDICAL...TAVERNETTI-

TENNANT-CUTTER KNEE PROSTHESIS...SIZE...SIDE...SERIAL NUMBER"

4. THE MODEL NUMBERS INVOLVED ARE FOR SMALL AND STANDARD SIZE PROSTHESES FOR BOTH RIGHT AND LEFT KNEES: TTC-10 (RIGHT SMALL); TTC-15 (LEFT SMALL); TTC-20 (RIGHT STANDARD) TTC-25 (LEFT STANDARD)

5. THE SERIAL NUMBERS ARE NUMEROUS AND NON-CONTINUOUS: ALL SERIAL NUMBERS BEGIN WITH "KB" IE. KBO58, KBO57

6. MANUFACTURER/RECALLING FIRM - CUTTER BIOMEDICAL DIVISION OF CUTTER LABORATORIES, INC., 7380 CONVOY COURT, SAN DIEGO, CALIFORNIA. THE COMPANY THAT PERFORMS THE STERILIZATION FOR CUTTER IS INTERNATIONAL NUTRONICS, 1237 N. SAN ANTONIO ROAD, PALO ALTO, CA 94303.

7. REASON FOR RECALL - THE DEVICE IS LABELED AS BEING "...UNSTERILE (IF INNER PACKAGE SEALED)" THE FIRM HAS LEARNED HOWEVER THAT THE GAMMA RADIATION, IN EXCESS OF 3.3 MEGA RADS, USED TO STERILIZE THE PRODUCT CAUSES THE PLASTIC CONTAINER TO BECOME BRITTLE AND PERFORATED IN SOME CASES. THE FIRM LEARNED OF THE PROBLEM DUE TO UNCLASSIFIED

TWO COMPLAINTS ON THE PROBLEM.

8. NO INJURIES OR DEATHS HAVE BEEN REPORTED. ACCORDING TO THE FIRM IT IS NORMAL HOSPITAL PRACTICE TO INSPECT THE DEVICES BEFORE USE AND ALSO USE HIGH DOSAGES OF ANTIBIOTICS BEFORE AND AFTER THE SURGERY.

9. FOREIGN CONSIGNEES WERE ADVISED BY LETTER DATED DECEMBER 2, 1977 THAT THEY WILL BE SENT NEW PACKAGING AND LABELS SO THAT THE DEVICE CAN BE REPACKAGED BY THEIR SALES REPRESENTATIVES. THE REPACKAGED ITEMS WILL BE MARKED CLEAN BUT NOT STERILE AS THEY WERE PRIOR TO MAY 1977.

10. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN ADVISED BY FIRM OF NECESSARY PROCEDURES TO CORRECT PROBLEM. ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE DIRECTED TO FIRM.

11. FOREIGN CONSIGNEES PROVIDED BY FIRM TO FDA ARE:

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Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

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Draft Date: 11 jul 1978
Decaption Date: 01 jan 1960
Decaption Note:
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Disposition Approved on Date:
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Disposition Comment:
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Disposition Event:
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Disposition Reason:
Disposition Remarks:
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TAGS: OGEN, ETRD, EIND, TBIO, SW, AS, UK
To: STOCKHOLM CANBERRA MULTIPLE
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/e1864977-c288-dd11-92da-001cc4696bcc
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